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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Donor Suitability Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Blood Donor Suitability Workshop.'' The purpose of the public workshop is to provide an open forum for discussion of specific donor suitability issues associated with donor deferrals.

Date and Time: The public workshop will be held on December 9, 1999, 8 a.m. to 5 p.m.

Location: The public workshop will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

For information regarding the public workshop and registration: Therese Burke, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703–351–7676, FAX 703–528–0716, E-mail: tburke@lcgnet.com.

Registration: Early registration is recommended on or before November 26, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Therese Burke (address above). Registration at the site will be done on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Therese Burke at least 7 days in advance.

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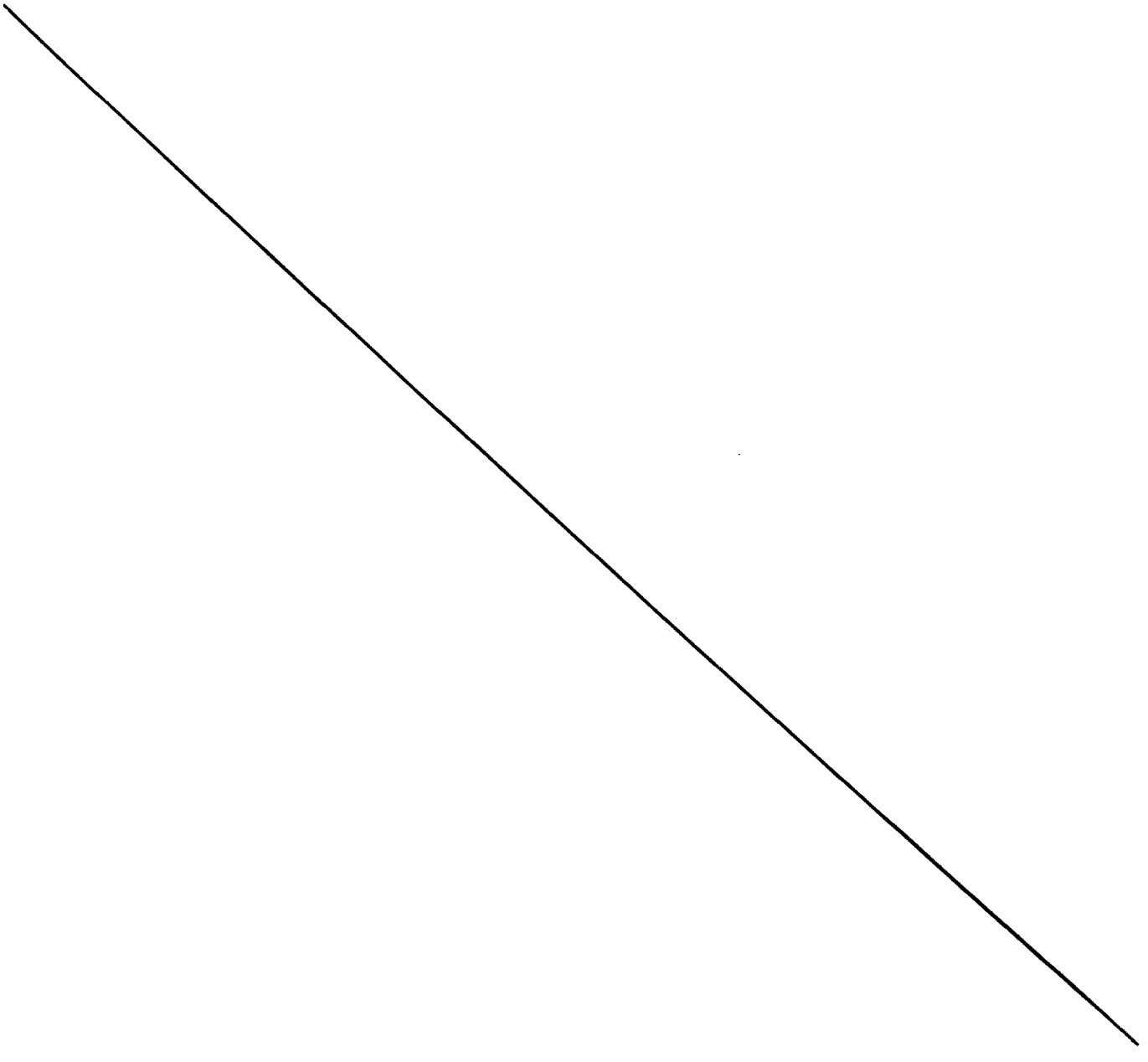
Agenda: FDA is holding a public workshop to gather scientific data on specific donor suitability issues affecting donor deferrals and to evaluate how these donor deferrals may affect the nation's blood supply. The three key topics to be discussed at the workshop include: (1) Donor deferral registries, including deferral registries that are used in-house, at mobile collection sites, as well as registries shared by several facilities; (2) minimum donor weight and adjustment of blood volume based on body weight; and (3) deferral of donors who have a history of cancer.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16,



Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. The public workshop transcript will also be available on the Center for Biologics Evaluation and Research website at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 11/17/99

November 17, 1999

William Hubbard

William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

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Michael W. Bell